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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/019,441	02/05/98	REFF M	012712-502

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EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	13

DATE MAILED: 04/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/019,441	Rebbeta-l
Examiner	**Group Art Unit**
Marianne DiBrin	1644

☒ Responsive to communication(s) filed on *Jan 28, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-41* is/are pending in the applicat

Of the above, claim(s) *26-39* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-25, 40, and 41* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☑ Notice to comply with Sequence Rules

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The search has been conducted on SEQ ID NOS: 1-4 using the Sequence Listing from the parent application serial no. 08/803,085.

2. Applicant's amendment, filed 1/28/00 (Paper No. 12), is acknowledged and has been entered.

Claims 9, 12, 13 and 25 have been amended.
Claims 40 and 41 have been added.
Claims 1-41 are pending and claims 1-25 and 40-41 are being acted upon presently.

The following are new grounds of rejection.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-9, 13-22 and 40-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Bonnefoy et al (WO 96/12741) as evidenced by Saxon et al (J. Immunol. Vol. 147 (11), 1991, pp 4000-4006).

Bonnefoy et al teaches a monoclonal humanized anti-CD23 antibody with a rodent antigen binding portion and which may be either an IgG1 or an IgG3 and pharmaceutical composition thereof (especially page 4, lines 1-3 and lines 15-19, page 5, lines 4-11 and 25-27 and cliams 11-15) which is useful for treating allergic diseases, including blocking an IgE immune response (especially page 8, lines 20-22 and claims 1-4). It is an inherent property of anti-CD23 antibodies to inhibit IgE expression as evidenced by Saxon et al (especially Abstract). Claims 8 and 21 are included because the ability to inhibit IgE expression in vivo is an inherent property of said antibodies because they have this property in vitro. It is an inherent property of said antibodies to bind to the human Fc gamma receptors. Claims 13 and 25 are included because it is an inherent property of said antibodies to block the binding of other anti-CD23 antibodies, either directly or indirectly. It is an inherent property of monoclonal antibodies to have a binding affinity within the range recited in claim 9.

6. Claims 1, 5-9, 13, 14, 17-22 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Newman et al (U.S. Patent No. 5,658, 570) as evidenced by Saxon et al (J. Immunol. Vol. 147 (11), 1991, pp 4000-4006).

Newman et al teach human, chimeric or humanized anti-CD23 antibodies which comprise a human constant region of IgG isotoype(especially claims 1-8 and column 8, lines 52-53). It is an inherent property of anti-CD23 antibodies to inhibit IgE expression as evidenced by Saxon et al (especially Abstract). Claims 8 and 21 are included because the ability to inhibit IgE expression in vivo is an inherent property of said antibodies because they have this property in vitro. It is an inherent property of said antibodies to bind to the human Fc gamma receptors. Claims 13 and 25 are included because it is an inherent property of said antibodies to block the binding of other anti-CD23 antibodies, either directly or indirectly.

The reference teachings anticipate the claimed invention.

7. Claims 1-11, 13-25, 40 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Queen et al (U.S. Patent No. 5,585,089) in view of Saxon et al (J. Immunol. Vol. 147 (11), 1991, pp 4000-4006).

Queen et al disclose humanized mAbs comprising a human constant region (especially column 12, lines 1-15), including IgG1 and IgG3 subclasses (especially column 11, lines 4-8), and a

mouse or rat antigen binding region (especially column 12, lines 1-15). Queen et al further disclose said antibodies have binding affinities of at least about 5nM or stronger (especially column 10, lines 57-63, i.e., at least about 10^8 M^{-1} = at least about 10nM) as well a mAb with a binding affinity of 100nM (especially column 56, lines 43). Queen et al also disclose the advantages of such humanized mAbs (especially column 1, lines 25-67 and continuing onto column 2, lines 1-10) including that they bind to the same antigen as the original antibodies, but are less immunogenic when injected into humans.

Queen et al do not disclose that said antibodies are anti-CD23 antibodies.

Saxon et al teach murine anti-CD23 mAbs 135 and 45, both of which are IgG1, that inhibit IL-4 induced IgE expression in vitro by human plasma cell line AF-10 and teach said antibodies in fluid that is compatible with in vivo use (especially page 4001, "mAb and IgE-IC" section and page 4002, second full paragraph). Saxon et al teach that anti-CD23 antibodies inhibit IgE expression (especially Abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a humanized version of the CD23 mAb of Saxon et al as per the disclosure of Queen et al.

One of ordinary skill in the art would have been motivated to do this because Saxon et al teach that anti-CD23 antibodies inhibit IgE expression and Queen et al disclose the advantage of lower immunogenicity of humanized antigens for therapy. Claims 8 and 21 are included because the ability to inhibit IgE expression in vivo is property of said antibodies because they have this property in vitro. Since said antibody has the IgG constant region, it binds to human Fc gamma receptors. Claims 13 and 25 are included because it is an inherent property of said antibodies to block the binding of other anti-CD23 antibodies, either directly or indirectly.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-25 and 40-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,011,138. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the claims of the '138 patent include the limitation "inhibits IL-4 induced IgE expression by B-cells in vitro to a greater extent than the anti-human CD23 monoclonal antibody and composition thereof, which lacks a human gamma-1 constant region", the claims of the instant application are drawn to an anti-CD23 monoclonal antibody and composition thereof, which binds to human Fc gamma receptors and inhibits IgE expression . The antibodies of the instant claims include either a gamma-1 or gamma-3 constant region, and would be expected to bind the Fc gamma receptor and inhibit IL-4 induced IgE expression to a greater extent than would antibodies lacking said constant regions.

10. Claims 1-25 and 40-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 09/292,053. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention of the'053 application, i.e., an anti-human CD23 monoclonal antibody comprising a human gamma-1 constant region, is encompassed by the claims of the instant application. Although the 5E8, 6G5 or 2C8 antibodies recited in the '053 application are not recited in the instant claims, SEQ ID NOS: 1-4 which are recited in the instant claims are derived from said antibodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claim 12 appears to be free of the prior art.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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April 17, 1999

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